REMARKS

Claims 1-11 are pending. Claims 1-11 are objected to and rejected.

Independent claims 1, 8, and 10 are currently amended. New claim 12 is added.

CLAIM OBJECTIONS

Claims 1-11 are objected to.

Applicants have amended independent claims 1, 8, and 10. Thus, all the claims identify the peptide as requested by the Examiner.

CLAIM REJECTIONS

CLAIM REJECTIONS UNDER 35 U.S.C. §112

Claims 1-11 are rejected under 35 U.S.C. §112, ¶ 1, as not enabled. The Examiner states that there is no nexus between SEQ ID NO:1 and hepatic injury, although finding that the specification discloses the identity and dose of the compound to administer, under what clinical conditions to administer it, and when to stop treatment.

Applicants respectfully assert that the claims are enabled, because the additional information discussed by the Examiner is not required to enable these claims.

The claims are not directed to the peptide's mechanisms of action. Therefore, one need not know the pharmacological or biochemical processes involved to know that the claimed method achieves a therapeutic response. The

specification discloses that the claimed method of decreasing or treating hepatic injury is assessed as effective by routine clinical chemistry values for hepatic function tests, which are known to one skilled in the art.

"A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. §112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." MPEP §2164.04 (emphasis added)

As previously analyzed, applicants claim a method to treat the cytokine response to hepatic injury by administering SEQ ID NO:1. Realization of the claimed treatment is determined by a routine serum chemistry panel whereby hepatic function parameters return to normal and are maintained at normal values (page 4, lines 9-19). The Examiner's assertion that it is undue experimentation to determine which specific cytokines are affected by SED ID NO:1, and how they are affected, is not within the claim scope. As such, applicants respectfully assert that the claimed invention is described and enabled.

Applicants further respectfully disagree that controls to determine side effects of the applicants' method are required. For example, MPEP §2107.03 V states that it is improper for the Patent Office to request evidence of safety in the treatment of humans, or regarding the degree of effectiveness.

Claims 1-11 are rejected under 35 U.S.C. §112, ¶2, as incomplete.

Independent claims 1, 8, and 10 are currently amended. The specific doses and durations recited in the dependent claims are further limitations on the inventive method.

CONCLUSION

Applicants believe the Examiner's rejections and objections have been overcome, and that the application is in complete condition for allowance. Applicants believe that no fees are due. However, should any fees or surcharges be deemed necessary, the Examiner has authorization to charge fees or credit any overpayment to Deposit Account No. 23-3000.

The Examiner is invited to telephone applicant's undersigned representative with any questions.

Respectfully submitted,

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